

WHAT IS CLAIMED IS:

1. A nucleic acid molecule comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the CEA fusion protein comprises a CEA protein or variant thereof, fused to a substantial portion of an immunoenhancing element selected from the group consisting of:
5 DOM, FcIgG, CT, LTA, and LTB; and wherein the fusion protein is capable of producing an immune response in a mammal.

2. The nucleic acid molecule of claim 1, wherein the CEA protein is a human CEA protein or variant thereof.

10

3. The nucleic acid molecule of claim 1, wherein the CEA protein is a rhesus monkey CEA protein or variant thereof.

15

4. The nucleic acid molecule of claim 1, wherein the CEA protein is C-terminally truncated.

5. The nucleic acid molecule of claim 4, wherein the C-terminal truncation comprises amino acids 679 – 702 of SEQ ID NO:20.

20

6. The nucleic acid molecule of claim 1, wherein the immunoenhancing element comprises a substantial portion of subunit A of heat labile enterotoxin of *E. coli* (LT).

7. The nucleic acid molecule of claim 1, wherein the immunoenhancing element comprises a substantial portion of subunit B of heat labile enterotoxin of *E. coli* (LT).

25

8. The nucleic acid molecule of claim 7, wherein the LT subunit B is truncated of its signal sequence.

30

9. The nucleic acid molecule of claim 1, wherein the immunoenhancing element comprises a substantial portion of DOM or FcIgG.

10. The nucleic acid molecule of claim 1, wherein the sequence of nucleotides comprises a sequence of nucleotides selected from the group consisting of SEQ ID NOs:7, 9, 11, 12, 14, 21, 25, 49, 50, and 52.

11. The nucleic acid molecule of claim 11, wherein the sequence of nucleotides comprises a sequence of nucleotides as set forth in SEQ ID NO:9, SEQ ID NO:11, or SEQ ID NO:12.

12. A nucleic acid molecule comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the sequence of nucleotides is as set forth in SEQ ID NO:12.

13. The nucleic acid molecule of claim 8, wherein the C-terminal end of the CEA protein is fused to the N-terminal end of LT subunit B.

10

14. A vector comprising the nucleic acid molecule of claim 1.

15. The vector of claim 14, wherein the vector is an adenovirus vector or a plasmid vector.

15

16. The vector of claim 15, wherein the vector is an Ad 5 vector.

17. The vector of claim 15, wherein the vector is an Ad 6 vector or an Ad 24 vector.

20

18. The vector of claim 15, wherein the vector is a chimp Ad vector.

19. The vector of claim 15, wherein the vector is pV1JnsB.

25

20. A host cell comprising the vector of claim 15.

21. A process for expressing a CEA fusion protein in a recombinant host cell, comprising:

30 (a) introducing a vector comprising the nucleic acid molecule of claim 1
into a suitable host cell; and,
(b) culturing the host cell under conditions which allow expression of
said human CEA fusion protein.

22. A purified CEA fusion protein encoded by the nucleic acid molecule of claim 1.

23. The purified CEA fusion protein of claim 22, wherein the fusion protein comprises a sequence of amino acids selected from the group consisting of : SEQ ID NOS:8, 10, 13, 15, 45, 46, 51, and 53.

24. A method of preventing or treating cancer comprising administering to a mammal a vaccine vector comprising the nucleic acid molecule of claim 1.

10

25. A method according to claim 24 wherein the mammal is human.

26. A method according to claim 25 wherein the vector is an adenovirus vector or a plasmid vector.

15

27. A method according to claim 26 wherein the vector is an adenoviral vector comprising an adenoviral genome with a deletion in the adenovirus E1 region, and an insert in the adenovirus E1 region, wherein the insert comprises an expression cassette comprising:

(a) a polynucleotide comprising sequence of nucleotides that encodes a CEA fusion protein, wherein the CEA fusion protein comprises a CEA protein or variant thereof, fused to a substantial portion of an immunoenhancing element selected from the group consisting of: DOM, FcIgG, CT, LTA, and LTB; and wherein the fusion protein is capable of producing an immune response in a mammal.; and,

(b) a promoter operably linked to the polynucleotide.

25

28. A method according to claim 26 wherein the vector is a plasmid vaccine vector, which comprises a plasmid portion and an expressible cassette comprising

(a) a polynucleotide comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the CEA fusion protein comprises a CEA protein or variant thereof, fused to a substantial portion of an immunoenhancing element selected from the group consisting of: DOM, FcIgG, CT, LTA, and LTB; and wherein the fusion protein is capable of producing an immune response in a mammal.; and,

(b) a promoter operably linked to the polynucleotide.

29. An adenovirus vaccine vector comprising an adenoviral genome with a deletion in the E1 region, and an insert in the E1 region, wherein the insert comprises an expression cassette comprising:

5 (a) a polynucleotide comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the CEA fusion protein comprises a CEA protein or variant thereof, fused to a substantial portion of an immunoenhancing element selected from the group consisting of: DOM, FcIgG, CT, LTA, and LTB; and wherein the fusion protein is capable of producing an immune response in a mammal; and

10 (b) a promoter operably linked to the polynucleotide.

30. An adenovirus vector according to claim 29 which is an Ad 5 vector.

31. An adenovirus vector according to claim 29 which is an Ad 6 vector or an Ad 24 vector.

15 32. A vaccine plasmid comprising a plasmid portion and an expression cassette portion, the expression cassette portion comprising:

20 (a) a polynucleotide comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the CEA fusion protein comprises a CEA protein or variant thereof, fused to a substantial portion of an immunoenhancing element selected from the group consisting of: DOM, FcIgG, CT, LTA, and LTB; and wherein the fusion protein is capable of producing an immune response in a mammal; and,

25 (b) a promoter operably linked to the polynucleotide.

33. A method of treating a mammal suffering from or predisposed to a CEA-associated cancer comprising:

(a) introducing into the mammal a first vector comprising:

30 (i) a polynucleotide comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the CEA fusion protein comprises a CEA protein or variant thereof, fused to a substantial portion of an immunoenhancing element selected from the group consisting of: DOM, FcIgG, CT, LTA, and LTB; and wherein the fusion protein is capable of producing an immune response in a mammal; and,

(ii) a promoter operably linked to the polynucleotide;

(b) allowing a predetermined amount of time to pass; and

- (c) introducing into the mammal a second vector comprising:
 - (i) a polynucleotide comprising a sequence of nucleotides that encodes a CEA fusion protein, wherein the CEA fusion protein comprises a CEA protein or variant thereof, fused to a substantial portion of an immunoenhancing element selected from the group consisting of:
 - 5 DOM, FcIgG, CT, LTA, and LTB; and wherein the fusion protein is capable of producing an immune response in a mammal; and
 - (ii) a promoter operably linked to the polynucleotide.

34. A method according to claim 33 wherein the first vector is a plasmid and the
10 second vector is an adenovirus vector.

35. A method according to claim 33 wherein the first vector is an adenovirus vector and the second vector is a plasmid.